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NEWS	4	FEB 28	BABS - Current-awareness alerts (SDIs) available
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NEWS	10	MAR 22	PATDPASPC - New patent database available
NEWS	11	MAR 22	REGISTRY/ZREGISTRY enhanced with experimental property tags
NEWS	12	APR 04	EPFULL enhanced with additional patent information and new fields
NEWS	13	APR 04	EMBASE - Database reloaded and enhanced
NEWS	14	APR 18	New CAS Information Use Policies available online
NEWS	15	APR 25	Patent searching, including current-awareness alerts (SDIs), based on application date in CA/CAplus and USPATFULL/USPAT2 may be affected by a change in filing date for U.S. applications.
NEWS	16	APR 28	Improved searching of U.S. Patent Classifications for U.S. patent records in CA/CAplus
NEWS	17	MAY 23	GBFULL enhanced with patent drawing images
NEWS	18	MAY 23	REGISTRY has been enhanced with source information from CHEMCATS
NEWS	19	JUN 06	The Analysis Edition of STN Express with Discover! (Version 8.0 for Windows) now available
NEWS	20	JUN 13	RUSSIAPAT: New full-text patent database on STN
NEWS	21	JUN 13	FRFULL enhanced with patent drawing images
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NEWS	23	JUL 01	MEDICONF removed from STN
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DRUGMONOG - IMS Product Monographs (Approved Pharm. Industry Users
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=> s oxycodone
L1 6318 OXYCODONE

=> s l1 and ibuprofen
L2 798 L1 AND IBUPROFEN

=> s l2 and 400 (w) mg
L3 53 L2 AND 400 (W) MG

=> duplicate remove l3
DUPLICATE IS NOT AVAILABLE IN 'DRUGMONOG2'.
ANSWERS FROM THESE FILES WILL BE CONSIDERED UNIQUE
DUPLICATE PREFERENCE IS 'CAPLUS, MEDLINE, EMBASE, BIOSIS, DRUGU'
KEEP DUPLICATES FROM MORE THAN ONE FILE? Y/(N):n
PROCESSING COMPLETED FOR L3
L4 23 DUPLICATE REMOVE L3 (30 DUPLICATES REMOVED)

=> d ibib abs 1-23

L4 ANSWER 1 OF 23 MEDLINE on STN DUPLICATE 1

ACCESSION NUMBER: 2005136939 MEDLINE
DOCUMENT NUMBER: PubMed ID: 15768621
TITLE: Oral analgesics for acute nonspecific pain.
AUTHOR: Sachs Carolyn J
CORPORATE SOURCE: University of California, Los Angeles, Emergency Medicine Center, Los Angeles, California, USA.. csachs@ucla.edu
SOURCE: American family physician, (2005 Mar 1) 71 (5) 913-8. Ref: 47
Journal code: 1272646. ISSN: 0002-838X.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
General Review; (REVIEW)
(REVIEW, TUTORIAL)
LANGUAGE: English
FILE SEGMENT: Abridged Index Medicus Journals; Priority Journals
ENTRY MONTH: 200504
ENTRY DATE: Entered STN: 20050317
Last Updated on STN: 20050406
Entered Medline: 20050405

AB Physicians most often recommend or prescribe oral medication for relief of acute pain. This review of the available evidence supports the use of acetaminophen in doses up to 1,000 mg as the initial choice for mild to moderate acute pain. In some cases, modest improvements in analgesic efficacy can be achieved by adding or changing to a nonsteroidal anti-inflammatory drug (NSAID). The safest NSAID is **ibuprofen** in doses of **400 mg**. Higher doses may offer somewhat greater analgesia but with more adverse effects. Other NSAIDs have failed to demonstrate consistently greater efficacy or safety than **ibuprofen**. Although they may be more expensive, these alternatives may be chosen for their more convenient dosing. Cyclooxygenase-2 inhibitors provide equivalent efficacy to traditional NSAIDs but lack a demonstrable safety advantage for the treatment of acute pain. For more severe acute pain, the evidence supports the addition of oral narcotic medications such as hydrocodone, morphine, or **oxycodone**. Specific oral analgesics that have shown poor efficacy and side effects include codeine, propoxyphene, and tramadol.

L4 ANSWER 2 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN DUPLICATE 2
ACCESSION NUMBER: 2005:478600 CAPLUS
TITLE: Analgesic efficacy and tolerability of **oxycodone** 5 mg/**ibuprofen 400 mg** compared with those of **oxycodone** 5 mg/acetaminophen 325 mg and hydrocodone 7.5 mg/acetaminophen 500 mg in patients with moderate to severe postoperative pain: A randomized, double-blind, placebo-controlled, single-dose, parallel-group study in a dental pain model
AUTHOR(S): Litkowski, Leonard J.; Christensen, Steven E.; Adamson, Dennis N.; Van Dyke, Thomas; Han, Seung-Ho; Newman, Kenneth B.
CORPORATE SOURCE: Center for Clinical Studies, Dental School, University of Maryland, Baltimore, MD, USA
SOURCE: Clinical Therapeutics (2005), 27(4), 418-429
CODEN: CLTHDG; ISSN: 0149-2918
PUBLISHER: Excerpta Medica, Inc.
DOCUMENT TYPE: Journal
LANGUAGE: English

AB Background: Combination therapy has been widely used for the clin. management of acute pain. By combining 2 drugs with different mechanisms of action, such therapy provides additive analgesic effects while reducing the risk for adverse effects. Objective: This study compared the efficacy and tolerability of **oxycodone** 5 mg/**ibuprofen 400 mg** with those of **oxycodone** 5 mg/acetaminophen 325 mg, hydrocodone 7.5 mg/acetaminophen 500 mg, and

placebo in a dental pain model. Methods: This was a multicenter, randomized, double-blind, placebo- and active-controlled, parallel-group, single-dose study in patients experiencing moderate to severe pain after surgical removal of ≥2 ipsilateral impacted third molars. Patients were randomly assigned to receive **oxycodone** 5 mg/**ibuprofen 400 mg**, **oxycodone** 5 mg/acetaminophen 325 mg, hydrocodone 7.5 mg/acetaminophen 500 mg, or placebo. The primary outcome measures were total pain relief through 6 h after dosing (TOTPAR6), sum of pain intensity differences through 6 h (SPID6), and adverse events. Secondary efficacy measures included SPID3 and TOTPAR3, peak pain relief, peak pain intensity difference, time to onset of pain relief, time to use of rescue medication, proportion of patients reporting pain half gone, and the patient's global evaluation. Results: Two hundred forty-nine patients (43.5% male; 87.5% white; mean age, 19.1 years; mean body weight, 153.6 lb) were randomized to treatment as follows: 62 to **oxycodone** 5 mg/**ibuprofen 400 mg**, 61 to **oxycodone** 5 mg/acetaminophen 325 mg, 63 to hydrocodone 7.5 mg/acetaminophen 500 mg, and 63 to placebo. **Oxycodone** 5 mg/**ibuprofen 400 mg** provided significantly greater analgesia compared with **oxycodone** 5 mg/acetaminophen 325 mg, hydrocodone 7.5 mg/acetaminophen 500 mg, and placebo (mean [SD] TOTPAR6, 14.98 [5.37], 9.53 [6.77], 8.36 [6.68], and 5.05 [6.49], resp.; P < 0.001, **oxycodone** 5 mg/**ibuprofen 400 mg** vs all other treatments). SPID6 values also differed significantly for **oxycodone** 5 mg/**ibuprofen 400 mg** compared with all other treatments (mean: 7.78 [4.11], 3.58 [4.64], 3.32 [4.73], and 0.69 [4.85]; P < 0.001). **Oxycodone** 5 mg/**ibuprofen 400 mg** was significantly more effective compared with the other treatments on all secondary end points (P < 0.001, all variables except peak PID vs **oxycodone** 5 mg/acetaminophen 325 mg [P = 0.006]), with the. Exception of the time to onset of analgesia. The lowest frequency of nausea and vomiting occurred in the groups that received **oxycodone** 5 mg/**ibuprofen 400 mg** (6.5% and 3.2%, resp.) and placebo (3.2% and 1.6%). Rates of nausea and vomiting were significantly lower with **oxycodone** 5 mg/**ibuprofen 400 mg** compared with **oxycodone** 5 mg/acetaminophen 325 mg (P = 0.011 and P = 0.009, resp.) but not with hydrocodone 7.5 mg/acetaminophen 500 mg. Conclusions: In this study in patients with moderate to severe pain after surgery to remove impacted third molars, **oxycodone** 5 mg/**ibuprofen 400 mg** provided significantly better analgesia throughout the 6-h study compared with the other opioid/nonopioid combinations tested, and was associated with fewer adverse events.

REFERENCE COUNT: 31 THERE ARE 31 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 3 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN DUPLICATE 3

ACCESSION NUMBER: 2005:261667 CAPLUS

DOCUMENT NUMBER: 143:1039

TITLE: Combination **oxycodone** 5 mg/**ibuprofen 400 mg** for the treatment of pain after abdominal or pelvic surgery in women: A randomized, double-blind, placebo- and active-controlled parallel-group study

AUTHOR(S): Singla, Neil; Pong, Annpey; Newman, Kenneth; Ahmad, Shireen; Barton, Scott R.; Berkowitz, Robert; Brody, Christine; Drass, Michael J.; Haddox, Linda; Head, James L.; Hemmings, Hugh C., Jr.; Houden, Timothy S.; Jones, Gary R.; Khaleghi, Behnam; Lyle, James E., III; Matsunaga, Mark Thomas; Mcdonald, Tillman Wayne; Moliver, Martin; Morgan, John; Quinn, Jeffrey D.; Ratnaraj, Jebadurai; Reynolds, Lowell W.; Rhondeau, Steve M.; Singla, Neil; Spencer, Ronald P.; Stavoy,

Thomas G.; Van Zandt, Sephanie; Wall, Jeffrey; Wideman, John G.; Wittmer, Brett A.

CORPORATE SOURCE: The MD-10 Study Group, Department of Anesthesia, Huntington Memorial Hospital, Pasadena, CA, USA

SOURCE: Clinical Therapeutics (2005), 27(1), 45-57
CODEN: CLTHDG; ISSN: 0149-2918
PUBLISHER: Excerpta Medica, Inc.
DOCUMENT TYPE: Journal
LANGUAGE: English

AB Background: The sensation of pain arises from both central and peripheral sites, and inflammation may be one of its underlying causes. Combination therapy with analgesic agents having multimodal mechanisms of action and complementary pharmacokinetic properties enhances pain relief by addressing the different pathways of pain while limiting individual drug doses and, therefore, the potential for adverse effects caused by any single agent. **Oxycodone** and **ibuprofen** each have been used effectively as monotherapy and in other combinations for the treatment of acute pain; a fixed combination of these analgesics may improve pain relief in the setting of abdominal or pelvic surgery, where trauma and any resultant inflammation may be present at the same time. Objective: This study evaluated and compared the analgesic efficacy and tolerability of a single-dose combination tablet containing **oxycodone** 5 mg/**ibuprofen 400 mg** with either agent alone and with placebo in women who had undergone abdominal or pelvic surgery. Methods: In this multicenter, randomized, double-blind, placebo- and active-controlled, parallel-group trial, women experiencing moderate to severe pain between 14 and 48 h after surgery were randomized per protocol to receive a single dose of study medication in a 3:3:1:1 ratio (combination **oxycodone/ibuprofen**, **ibuprofen**, **oxycodone**, and placebo, in that order). Over a 6-h study period, patients recorded their assessments of pain intensity (100-mm visual analog scale and 4-point scale), relief from starting pain, and overall evaluation of study drug based on prespecified definitions and rating scales. Based on these data, the following primary efficacy end points were determined: total pain relief 6 h after dosing (TOTPAR6) and sum of pain intensity differences 6 h after dosing (SPID6). Other end points included the time to onset of pain relief, time to use of rescue medication, and patient's global rating of analgesic effectiveness. Tolerability was evaluated on the basis of observed and patient-reported adverse events and findings on phys. examination Results: Four hundred fifty-six women participated in the study. They were primarily white and had a mean age of 41.6 years and a mean body weight of 171.5 lb. Combination treatment was associated with significantly better TOTPAR6 and SPID6 scores compared with **ibuprofen** alone ($P < 0.02$ and $P < 0.015$, resp.), **oxycodone** alone ($P < 0.009$ and $P < 0.001$), or placebo (both, $P < 0.001$). Fewer patients receiving combination treatment required rescue medication, and the time to use of rescue medication was significantly longer in the combination-treatment group compared with the other groups ($P < 0.05$). Patients' global ratings of analgesic efficacy were significantly higher in the combination-treatment group compared with all other groups ($P < 0.044$ vs **ibuprofen** alone; $P < 0.001$ vs **oxycodone** alone and placebo). The onset of pain relief occurred within 15 min of dosing with all 4 regimens. Nausea was the most frequently reported treatment-emergent adverse event in all 4 groups. The incidence of treatment-emergent adverse events was highest with placebo (55.0%), followed by **oxycodone** alone.

REFERENCE COUNT: 24 THERE ARE 24 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 4 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN

ACCESSION NUMBER: 2004:430288 CAPLUS
DOCUMENT NUMBER: 140:429017
TITLE: Drug condensation aerosols and kits
INVENTOR(S): Hale, Ron L.; Hodges, Craig C.; Lloyd, Peter M.; Lu,

Amy T.; Myers, Daniel J.; Rabinowitz, Joshua D.; Wensley, Martin J.

PATENT ASSIGNEE(S): Alexza Molecular Delivery Corporation, USA

SOURCE: U.S. Pat. Appl. Publ., 84 pp., Cont.-in-part of U.S. Ser. No. 633,877.
CODEN: USXXCO

DOCUMENT TYPE: Patent

LANGUAGE: English

FAMILY ACC. NUM. COUNT: 31

PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
US 2004099269	A1	20040527	US 2003-718982	20031120
US 2003051728	A1	20030320	US 2001-57198	20011026
US 2003015197	A1	20030123	US 2002-146088	20020513
US 2003017115	A1	20030123	US 2002-146516	20020513
US 6737042	B2	20040518		
US 2003035776	A1	20030220	US 2002-146515	20020513
US 6682716	B2	20040127		
US 2003209240	A1	20031113	US 2002-146086	20020513
US 2003007933	A1	20030109	US 2002-150267	20020515
US 6797259	B2	20040928		
US 2003007934	A1	20030109	US 2002-150268	20020515
US 6780399	B2	20040824		
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US 6855310	B2	20050215		
US 2003206869	A1	20031106	US 2002-151626	20020516
US 6783753	B2	20040831		
US 2003017116	A1	20030123	US 2002-150857	20020517
US 6716415	B2	20040406		
US 2003021753	A1	20030130	US 2002-150591	20020517
US 6780400	B2	20040824		
US 2003005924	A1	20030109	US 2002-152652	20020520
US 6740307	B2	20040525		
US 2003012740	A1	20030116	US 2002-153139	20020520
US 6814954	B2	20041109		
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US 2003000518	A1	20030102	US 2002-155097	20020523
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US 2003015190	A1	20030123	US 2002-154594	20020523
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US 2003017114	A1	20030123	US 2002-154765	20020523
US 6814955	B2	20041109		
US 2003118512	A1	20030626	US 2002-280315	20021025
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US 2004184999	A1	20040923	US 2004-768220		20040129
US 2004185000	A1	20040923	US 2004-768293		20040129
US 2004185003	A1	20040923	US 2004-769157		20040129
US 2004185004	A1	20040923	US 2004-769197		20040129
US 2004202617	A1	20041014	US 2004-768281		20040129
US 2004185001	A1	20040923	US 2004-769046		20040130
US 2004185002	A1	20040923	US 2004-769051		20040130
US 2004161385	A1	20040819	US 2004-775586		20040209
US 2004167228	A1	20040826	US 2004-775583		20040209
US 2004170569	A1	20040902	US 2004-791915		20040303
US 2004170570	A1	20040902	US 2004-792012		20040303
US 2004170572	A1	20040902	US 2004-792096		20040303
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US 2004186130	A1	20040923	US 2004-813722		20040331
US 2004191183	A1	20040930	US 2004-814690		20040331
US 2004191184	A1	20040930	US 2004-814998		20040331
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PRIORITY APPLN. INFO.:			US 2001-57197	A2	20011026
			US 2001-57198	A2	20011026
			US 2001-332279P	P	20011121
			US 2001-332280P	P	20011121
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			US 2002-146088	A2	20020513
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US 2002-153139	A2	20020520
US 2002-153311	A2	20020521
US 2002-153313	B2	20020521
US 2002-153831	A2	20020521
US 2002-153839	A2	20020521
US 2002-155373	A2	20020522
US 2002-155621	A2	20020522
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US 2002-154594	A2	20020523
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US 2002-280315	A2	20021025
US 2002-302010	A2	20021121
US 2002-302614	A2	20021121
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US 2003-633876	A2	20030804
US 2003-633877	A2	20030804
US 2001-294203P	P	20010524
US 2001-296225P	P	20010605
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US 2003-749539	A1	20031230
US 2003-749783	A1	20031230
US 2003-750303	A1	20031230

AB The present invention provides novel condensation aerosols for the treatment of disease and/or intermittent or acute conditions. These condensation aerosols have little or no pyrolysis degradation products and are characterized by having an MMAD of between 1-3 μ. The aerosols are made by rapidly heating a substrate coated with a thin film of drug having a thickness of between 0.05 and 20 μm, while passing a gas over the film, to form particles of a desirable particle size for inhalation. Kits comprising a drug and a device for producing a condensation aerosol are also provided. The device contained in the kit typically, has an element for heating the drug which is coated as a film on the substrate and contains a therapeutically ED of a drug when the drug is administered in aerosol form, and an element allowing the vapor to cool to form an aerosol. Also disclosed, are methods for using these aerosols and kits. For example, acebutolol (MW 336, m.p. 123°, oral dose **400 mg**), a β-adrenergic blocker (cardiovascular agent), was coated on a stainless steel cylinder (8 cm). The drug (0.89 mg) was applied to the substrate, for a calculated drug film thickness of 1.1 μm. The substrate was heated at 20.5 V and purity of the drug aerosol particles was determined to be 98.9%; 0.53 mg was recovered from the filter after vaporization, for a percent yield of 59.6%. A total mass of 0.81 mg was recovered from the test apparatus and substrate, for a total recovery of 91%. High speed photographs were taken as the drug-coated substrate was heated to monitor visually formation of a thermal vapor. The photographs showed that a thermal vapor was initially visible 30 ms after heating was initiated, with the majority of the thermal vapor formed by 130 ms. Generation of the thermal vapor was complete by 500 ms.

L4 ANSWER 5 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN DUPLICATE 4
ACCESSION NUMBER: 2004:966276 CAPLUS
DOCUMENT NUMBER: 142:290366
TITLE: Lumiracoxib
AUTHOR(S): Lyseng-Williamson, Katherine A.; Curran, Monique P.
CORPORATE SOURCE: Adis International Limited, Auckland, N. Z.
SOURCE: Drugs (2004), 64(19), 2237-2246
CODEN: DRUGAY; ISSN: 0012-6667
PUBLISHER: Adis International Ltd.
DOCUMENT TYPE: Journal; General Review
LANGUAGE: English
AB A review. Lumiracoxib is a highly selective and potent cyclooxygenase (COX)-2 inhibitor, with a novel structure that conveys weakly acidic properties and a unique pharmacol. profile. It is rapidly absorbed, with a relatively short plasma half-life. In well designed clin. trials of 1-52 wk' duration in patients with osteoarthritis (OA) or rheumatoid arthritis, the efficacy of oral lumiracoxib 100-**400 mg** /day in decreasing pain intensity and improving functional status was greater than that with placebo and similar to those with nonselective NSAIDs or celecoxib 200mg once daily. In single- and multiple-dose well designed trials in patients with acute pain associated with primary dysmenorrhoea, dental or orthopedic surgery or tension-type headache, lumiracoxib 100-800mg once daily was more effective in relieving acute pain than placebo or controlled-release **oxycodone** 20mg, and was at least as effective as selective COX-2 inhibitors or nonselective NSAIDs. Lumiracoxib was generally well tolerated in clin. trials, with a similar overall tolerability profile to those of placebo and other COX-2-selective inhibitors. In a large 52-wk safety trial in patients with OA, lumiracoxib 400mg once daily had a rate of gastrointestinal ulcer complications that was approx. one-third to one-quarter of that of **ibuprofen** 800mg three times daily or naproxen 500mg twice daily. Lumiracoxib was not associated with an increase in cardiovascular events.
REFERENCE COUNT: 44 THERE ARE 44 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 6 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN DUPLICATE 5
ACCESSION NUMBER: 2005:151882 CAPLUS
DOCUMENT NUMBER: 142:348080
TITLE: Pharmacokinetic properties of combination **oxycodone** plus racemic **ibuprofen**: two randomized, open-label, crossover studies in healthy adult volunteers
AUTHOR(S): Kapil, Ram; Nolting, Arno; Roy, Partha; Fiske, William; Benedek, Irma; Abramowitz, Wattanaporn
CORPORATE SOURCE: Forest Research Institute, Jersey City, NJ, USA
SOURCE: Clinical Therapeutics (2004), 26(12), 2015-2025
CODEN: CLTHDG; ISSN: 0149-2918
PUBLISHER: Excerpta Medica, Inc.
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Background: As part of ongoing studies to evaluate the analgesic efficacy and pharmacokinetic properties of combination **oxycodone** plus **ibuprofen** in the treatment of moderate to severe acute pain, 2 pharmacokinetic studies were conducted. Objectives: The goals of these studies were to compare the pharmacokinetic properties of monotherapy with **oxycodone** or **ibuprofen** with those of a tablet formulation of these 2 agents combined (study A), and to determine whether the absorption of the individual agents when given in the combination tablet was affected by the concomitant ingestion of food (study B). Methods: Study A was a single-center, open-label, randomized, single-dose, 3-period, 3-way, crossover study. Healthy male subjects received **oxycodone** 5 mg, **ibuprofen 400 mg**, or a combination tablet containing both, after an overnight fast of ≥8 h,

on study days 1, 8, and 15. Study B was a single-center, open-label, randomized, single-dose, single-crossover study. Healthy volunteers received a tablet containing a combination of **oxycodone** 5 mg plus **ibuprofen 400 mg** after either an overnight fast of ≥8 h or a standardized high-fat breakfast. Both studies included a washout period of ≥7 days between treatments. In both studies, the pharmacokinetic properties (Cmax, Tmax, t1/2, AUC0-4, AUC0-t, and AUC0-∞) of **oxycodone** and **ibuprofen** were derived from plasma drug concns. Anal. of variance was used to determine and compare pharmacokinetic properties. Results: Twenty-four healthy, white, male subjects were included in study A (mean age, 26.0 years; mean body weight, 71.3 kg; mean height, 170.0 cm). Study B involved 12 subjects (11 men, 1 woman; mean age, 24.8 years; mean body weight, 77.2 kg; mean height, 181.4 cm). The pharmacokinetic properties of **ibuprofen** and **oxycodone** were not statistically different when administered alone or combined. Food intake did not affect the rate of **oxycodone** absorption (90% CI of Cmax of fasted state vs fed state, 103-130), or the rate (90% CI of Cmax of fasted state vs fed state, 72-95) or extent (90% CI of AUC0-∞ of fasted state vs fed state, 88-102) of **ibuprofen** absorption. The extent of **oxycodone** absorption was slightly increased when the combination was given with food (90% CI of AUC0-∞ of fasted state vs fed state, 115-127). Conclusions: The single-dose pharmacokinetic profiles of **oxycodone** and **ibuprofen** in these healthy volunteers were similar when these 2 drugs were given as monotherapy or in combination, suggesting bioequivalence. Food intake before administration of a single dose of the combination did not affect **ibuprofen** absorption but marginally increased the extent, but not the rate, of **oxycodone** absorption.

REFERENCE COUNT: 29 THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 7 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN DUPLICATE 6

ACCESSION NUMBER: 2005:151881 CAPLUS
DOCUMENT NUMBER: 142:456825
TITLE: Combination **oxycodone** 5 mg/**ibuprofen 400 mg** for the treatment of postoperative pain: a double-blind, placebo-and active-controlled parallel-group study
AUTHOR(S): Van Dyke, Thomas; Litkowski, Leonard J.; Kiersch, Theodore A.; Zarringhalam, Nooshin Majd; Zheng, Hongjie; Newman, Kenneth
CORPORATE SOURCE: Boston University Goldman School of Dental Medicine, Boston, MA, USA
SOURCE: Clinical Therapeutics (2004), 26(12), 2003-2014
CODEN: CLTHDG; ISSN: 0149-2918
PUBLISHER: Excerpta Medica, Inc.
DOCUMENT TYPE: Journal
LANGUAGE: English

AB This study compared the efficacy and safety of a single dose of **oxycodone** 5 mg/**ibuprofen 400 mg** vs. its individual components and placebo in a third-molar extraction model. In this multicenter, double-blind, double-dummy, parallel-group investigation, subjects with moderate to severe pain within 5 h after extraction of ≥2 ipsilateral bony impacted third molars were randomized to single doses of **oxycodone** 5 mg/**ibuprofen 400 mg**, **ibuprofen 400 mg**, **oxycodone** 5 mg, or placebo. Primary efficacy variables were the sum of pain intensity difference over 6 h (SPID6) and total pain relief through 6 h (TOTPAR6). The pharmacokinetics of **oxycodone** and **ibuprofen**, alone and in combination, were also determined in a subset of patients. A total of 498 subjects were randomized to treatment (187 to **oxycodone** 5 mg/**ibuprofen 400 mg**, 186 to **ibuprofen 400 mg**, 63 to **oxycodone** 5 mg, and 62 to placebo). Baseline demographics were generally similar

among treatment groups, despite differences in sex (P = 0.041) and race (P = 0.023). Combination therapy was associated with greater analgesia than **ibuprofen** alone, **oxycodone** alone, or placebo (mean [SE] TOTPAR6: 13.3 [0.52], 12.2 [0.52], 4.3 [0.82], and 4.2 [0.83], resp. [P < 0.001 vs **oxycodone** or placebo, P = 0.012 vs **ibuprofen**]; mean [SE] SPID6: 6.54 [0.42], 5.41 [0.44], 0.14 [0.60], and 0.32 [0.59], resp. [P < 0.001 vs **oxycodone** or placebo, P = 0.002 vs **ibuprofen**]). Combination therapy was well tolerated. Pharmacokinetic results implied no interaction between **oxycodone** and **ibuprofen.** In this study, a single dose of **oxycodone** 5 mg/**ibuprofen 400 mg** was fast-acting, effective, and well tolerated in subjects with moderate to severe pain after dental surgery. **Oxycodone** 5 mg alone did not provide an efficacy benefit over placebo in this study.

REFERENCE COUNT: 35 THERE ARE 35 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 8 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN DUPLICATE 7

ACCESSION NUMBER: 2004:647392 CAPLUS

DOCUMENT NUMBER: 141:288911

TITLE: Systematic review of the analgesic efficacy and tolerability of COX-2 inhibitors in post-operative pain control

AUTHOR(S): Chen, L.-C.; Elliott, R. A.; Ashcroft, D. M.

CORPORATE SOURCE: School of Pharmacy and Pharmaceutical Sciences, The University of Manchester, Manchester, UK

SOURCE: Journal of Clinical Pharmacy and Therapeutics (2004), 29(3), 215-229
CODEN: JCPTED; ISSN: 0269-4727

PUBLISHER: Blackwell Publishing Ltd.

DOCUMENT TYPE: Journal

LANGUAGE: English

AB Objective: To evaluate the relative analgesic efficacy and tolerability of single-dose COX-2 inhibitors in post-operative pain management. Method: Systematic review of randomized controlled trials (RCTs). Outcome measures: The area under the pain relief vs. time curve was used to evaluate the proportion of patient achieving at least 50% pain relief using validated equations. The proportions of patients experiencing any adverse event or specific adverse events were also examined Results: In all, 18 RCTs were included which contained 2783 patients. The results of the effects of single-dose analgesics on the basis of 50% of patients achieving pain relief over 6 h from dental pain models suggested that oral rofecoxib 50 mg was more effective than codeine/paracetamol 60/600 mg, and the rate ratio (RR) was 2.11 (95% CI 1.6-2.75). Valdecoxib 40 mg was also more effective than **oxycodone**/paracetamol 10/1000 mg (RR 1.34; 95% CI 1.11-1.62). There was no significant differences between other oral COX-2 inhibitors and non-selective non-steroidal antiinflammatory drugs (NSAIDs), except that celecoxib 200 mg was less effective than **ibuprofen 400 mg** (RR 0.66; 95% CI 0.48-0.90) and rofecoxib 50 mg (RR 0.65; 95% CI 0.49-0.87). The results from orthopedic pain model showed no significant difference between rofecoxib 50 mg and naproxen sodium 550 mg (RR 1.04; 95% CI 0.73-1.49). The adverse effects of single-dose COX-2 inhibitor used in short-term post-operative pain management were generally mild and less than non-selective NSAIDs, although there was no significant difference. Conclusions: The analgesic efficacy and tolerability of single-dose COX-2 inhibitors were more effective than opioid-containing analgesics and similar to non-selective NSAIDs in post-operative pain management. Further studies are needed to examine the efficacy and tolerability of COX-2 inhibitors compared against active comparators over a longer duration to assess whether these short-term effects are mirrored by longer-term outcomes and to determine their ultimate risk-benefit profile.

REFERENCE COUNT: 49 THERE ARE 49 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 9 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN
ACCESSION NUMBER: 2004:21592 CAPLUS
DOCUMENT NUMBER: 140:70137
TITLE: Profile of NSAID + opioid combination analgesics
AUTHOR(S): Sunshine, Abraham
CORPORATE SOURCE: Analgesic Development Ltd. and NYU School of Medicine, New York, NY, USA
SOURCE: Pain (2003), 491-497. Editor(s): Bountra, Chas; Munglani, Rajesh; Schmidt, William K. Marcel Dekker, Inc.: New York, N. Y.
CODEN: 69EYYH; ISBN: 0-8247-8865-6
DOCUMENT TYPE: Conference; General Review
LANGUAGE: English
AB A review. In the management of acute pain and cancer pain, stepped levels of treatment intensity are recommended. The initial treatment is usually a nonopioid- analgesic, such as aspirin, salicylate salt, acetaminophen, or a nonsteroidal antiinflammatory drug (NSAID). If this treatment, at the recommended doses is inadequate, simply increasing the dose will not result in a proportional increase in analgesia. Furthermore, the risk of adverse effects increases with these higher doses. Therefore, the addition of a low-dose opioid is recommended. The combination can be given as two individual doses or in a combination tablet or capsule. The currently marketed analgesic combinations for pain in the United States are mixts. of either codeine, hydrocodone, **oxycodone**, or propoxyphene with aspirin, acetaminophen, or **ibuprofen**. **Ibuprofen** at 200 mg has an analgesic efficacy equal to or greater than aspirin or acetaminophen 650 mg. **Ibuprofen** at **400 mg** is widely considered to have a higher level of analgesic activity than aspirin or acetaminophen at 650 mg. Hence, it is reasonable that a **400-mg ibuprofen** combination with a low-dose opioid would undoubtedly have greater efficacy than a combination of 650 mg of aspirin or acetaminophen with the same amount of the opioid. For approval to market a combination product, the policy of the U.S. Federal Drug Administration (FDA) requires a clin. trial in which the efficacy of the combination is significantly better than both of the individual ingredients, and that the marketed NSAID alone is significantly better than placebo. The first successful NSAID-opioid NDA approved was for Vicoprofen, a combination containing 200 mg of **ibuprofen** and 7.5 mg of hydrocodone. When an NSAID (**ibuprofen**) combination is preferred the only one approved in the United States at this time is **ibuprofen** with hydrocodone (Vicoprofen). In clin. practice it would seem reasonable to initially administer the Vicoprofen with an addnl. 200 mg of **ibuprofen** to obtain the maximum benefit of the **ibuprofen** analgesia. If addnl. analgesia is required, and if the patient tolerated a single tablet of Vicoprofen, the clinician could carefully consider giving two Vicoprofen tablets at one time. This would provide **400 mg** of **ibuprofen** and 15 mg of hydrocodone. However, the approved dosage is not to exceed five tablets in 24 h. In summary, opioid-NSAID combination analgesics are indicated in the management of pain and form an intermediate step on the WHO ladder.
REFERENCE COUNT: 13 THERE ARE 13 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 10 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 2003-22005 DRUGU P G
TITLE: The effect of food on the absorption of an **oxycodone /ibuprofen** combination tablet following a single dose administration.
AUTHOR: Kapil R; Nolting A; Roy P; Abramowitz W
CORPORATE SOURCE: Forest; Merck-Darmstadt
LOCATION: Jersey City, N.J., USA; Ger.
SOURCE: Clin.Pharmacol.Ther. (73, No. 2, P82, 2003) 1 Tab.
CODEN: CLPTAT ISSN: 0009-9236

AVAIL. OF DOC.: Forest Laboratories, Jersey City, NJ, U.S.A.
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 2003-22005 DRUGU P G
AB Food had little or no effect on absorption of **oxycodone** (OXY) and **ibuprofen** (IBU) following single dose of fixed combination tablet in 12 subjects. This combination is under development as analgesic agent. (conference abstract: Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Washington, D.C., USA, April 2-5, 2003).
ABEX Methods Subjects were recruited into a randomized crossover trial during which they received OXY/IBU (5 mg/**400 mg**) after standardized high-fat breakfast (fed) and 10-hr overnight fast (fasted) on separate occasions at 7 days apart. Serial blood samples were collected for 24 hr and analyzed for each drug. Results Cmax, AUC, Tmax and half-life of each drug did not differ appreciably between fasted and fed states. However, Tmax of OXY was slightly longer in fed state. (E42/JM)

L4 ANSWER 11 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 2003-21920 DRUGU P
TITLE: Comparison of bioequivalency of single-dose **oxycodone** /**ibuprofen** combination with **oxycodone** or **ibuprofen** alone.
AUTHOR: Kapil R; Nolting A; Roy P; Fiske W; Benedek I H; Abramowitz W
CORPORATE SOURCE: Forest; Merck-Darmstadt; Bristol-Squibb
LOCATION: Jersey City, N.J., USA
SOURCE: Clin.Pharmacol.Ther. (73, No. 2, P46, 2003) 1 Tab.
CODEN: CLPTAT ISSN: 0009-9236
AVAIL. OF DOC.: Bristol-Myers Squibb PRI, Jersey City, NJ, U.S.A.
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 2003-21920 DRUGU P
AB The pharmacokinetics of **oxycodone** and **ibuprofen** after combined administration were studied in a randomized crossover trial. 24 Healthy males received **oxycodone** 5 mg, **ibuprofen** **400 mg**, or the combination on 3 separate days with 7 days washout. The Cmax, AUC, Tmax and half-life of neither drug was affected by concomitant administration of the other drug. (conference abstract: Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Washington, D.C., USA, April 2-5, 2003). (No EX).
ABEX (E33/JB)

L4 ANSWER 12 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 2001-42675 DRUGU T M S
TITLE: Amphotericin B-induced seizures in a patient with AIDS.
AUTHOR: Aruna A S; Al Samarrai S A; Al Humaidan A S
CORPORATE SOURCE: Univ.Louisiana-Xavier; Univ.Louisiana
LOCATION: New Orleans; Monroe, La., USA
SOURCE: Ann.Pharmacother. (35, No. 9, 1037-41, 2001) 1 Fig. 2 Tab. 21 Ref.
CODEN: APHRER ISSN: 1060-0280
AVAIL. OF DOC.: College of Pharmacy, Xavier University of Louisiana, 1 Drexel Dr., New Orleans, LA 70125-1098, U.S.A. (e-mail: aaruna@aol.com).
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature

AN 2001-42675 DRUGU T M S
AB A case amphotericin-B (AMB)-induced grand- and petit-mal seizures is reported in an AIDS patient with crytococcus meningitis. The patient was HIV-positive and was on p.o. didanosine, i.v. pentamidine, and p.o. hydroxyzine before admission. Her received i.v. piggyback AMB and became febrile. He received i.v. piggyback hydrocortisone, **ibuprofen**, and acetaminophen. He experienced 3 episodes of tonic-clonic seizures following AMB. During this period, he received i.v. piggyback lorazepam, i.m. meperidine, prochlorperazine suppositories, and p.o. phenytoin. AMB was replaced with p.o. fluconazole and didanosine was discontinued. No seizures were observed during this switch in treatment. However, the patient eventually died. His other medications included potassium Cl, furosemide, metoclopramide, magnesium oxide, diazepam, **oxycodone**, clotrimazole, and ketorolac tromethamine.
ABEX A 46-yr-old HIV-positive African-American man was admitted for evaluation of cryptococcal meningitis on May 20, 1993. At this time, he was taking p.o. didanosine (150 mg, b.i.d.), i.v. pentamidine (300 mg every 4 weeks), and p.o. hydroxyzine (50 mg, b.i.d.). On May 21, the patient received i.v. piggyback AMB (10 mg) over 30 min as a loading dose and 20 mg i.v. piggyback over 4 hr as maintenance. He was febrile and had elevated body temperature following the AMB test dose. He received i.v. piggyback hydrocortisone (30 mg) and **ibuprofen** (600 mg). He was also premedicated with i.v. piggyback hydrocortisone (30-70 mg) and p.o. acetaminophen (650 mg). During an AMB infusion, he experienced an episode of tonic-clonic seizure and received i.v. piggyback lorazepam (3 mg). He received i.m. meperidine (25 mg) for chills and prochlorperazine (25 mg x 2) suppositories for nausea and vomiting following a 2nd episode of seizure on May 25. On May 26, AMB was stopped and p.o. phenytoin (**400 mg**, b.i.d.) for 1 day as a loading dose and lorazepam (3 mg). On May 27, he was rechallenged with AMB and a 3rd seizure occurred. On June 1, AMB was again stopped and substituted with p.o. fluconazole. Didanosine was also discontinued. On June 2, he received a loading dose of fluconazole (800 mg) and fluconazole (**400 mg**/day) as maintenance. No seizures occurred. However, the patient's condition worsened and he died 2 wk after admission. The other medications prescribed during treatment were p.o. potassium Cl, i.v. piggyback furosemide, p.o. metoclopramide, p.o. magnesium oxide, i.v. piggyback diazepam, p.o. **oxycodone**, p.o. clotrimazole, and i.m. ketorolac tromethamine. (ABD/FY)

L4 ANSWER 13 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 2000-27231 DRUGU T E S
TITLE: Combination hydroxycodone and **ibuprofen** versus combination **oxycodone** and acetaminophen in the treatment of postoperative obstetric or gynecologic pain.
AUTHOR: Palangio M; Wideman G L; Keffer M; Landau C J; Morris E; Doyle R T; Jiang J G; Damask M; de Padova A
CORPORATE SOURCE: Knoll
LOCATION: Mount Olive, N.J.; Birmingham, Ala., USA
SOURCE: Clin.Ther. (22, No. 5, 600-12, 2000) 3 Fig. 3 Tab. 36 Ref.
CODEN: CLTHDG ISSN: 0149-2918
AVAIL. OF DOC.: Knoll Pharmaceutical Company, 3000 Continental Drive - North, Mount Olive, New Jersey 07828-1234, U.S.A. (e-mail: palangm@basf.com).
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 2000-27231 DRUGU T E S
AB The effects of combination hydrocodone barbiturate + **ibuprofen** (H+I, Vicoprofen, Knoll) and **oxycodone** HCl + acetaminophen (O+A, Percocet, Endo) were compared in a randomized, double-blind, single-dose, placebo-controlled study in 180 patients with postoperative obstetric or gynecologic pain. The pain relief (PR), total pain relief

(TOTPAR), and pain intensity difference (PID) scores were greater in the H+I group compared with the O+A group. All scores, including the sum of pain intensity differences (SPID), were greater and the time to onset of analgesia was lower in the active groups when compared with the placebo group. The adverse-events reported during the study included nausea, headache, pruritus, nervousness, flatulence, abnormal dreams, sweating, dizziness, amblyopia, asthenia and vasodilation.

ABEX Methods 180 Patients with moderate to severe postoperative obstetric or gynecologic pain were randomized in a double-blind manner to receive a single dose of combination H+I (15 mg/400 mg, n=61, mean age 41.8 yr), combination O+A (10 mg/650 mg, n=59, mean age 41.7 yr), or placebo (n=60, mean age 41 yr). Results Mean PR (at 5, 6 and 8 hr), PID (at 5-8 hr), and TOTPAR scores (at 0-6 and 0-8 hr) were greater with H+I than O+A. The scores of both active treatment groups were greater than those of the placebo group. The SPID scores for H+I and O+A were greater than the placebo group. The median time to onset of analgesia was 12.6, 15.4 and 29.5 min in the H+I, O+A and placebo groups, respectively. The mean peak PR score was 3.21, 2.98 and 1.23, respectively. The median time to remedication in the H+I, O+A and placebo groups was 4, 3.75 and 1 hr, respectively. The mean global assessment scores were 3.08, 2.80 and 1.47, respectively. Nausea was the most frequent adverse-event. Headache was also reported by all 3 groups. Pruritus and nervousness were only reported in the active treatment groups. Adverse-events only reported in the H+I group were flatulence, abnormal dreams, and sweating. Other adverse-events reported in the O+A group were dizziness, amblyopia, asthenia and vasodilation. Other adverse-events reported in the placebo group were flatulence and dyspepsia. (FY)

L4 ANSWER 14 OF 23 MEDLINE on STN DUPLICATE 8

ACCESSION NUMBER: 2001305873 MEDLINE
DOCUMENT NUMBER: PubMed ID: 11108567
TITLE: Transurethral microwave thermotherapy of the prostate without intravenous sedation: results of a single United States center using both low- and high-energy protocols. TJUH TUMT Study Group.
AUTHOR: Rivas D A; Bagley D; Gomella L G; Hirsch I H; Hubert C; Lombardo S; McGinnis D E; Mulholland S G; Shenot P J; Strup S E; Vasavada S P
CORPORATE SOURCE: Department of Urology, Jefferson Medical College, Thomas Jefferson University, Philadelphia 19107, USA.
SOURCE: Techniques in urology, (2000 Dec) 6 (4) 282-7.
Journal code: 9508161. ISSN: 1079-3259.
PUB. COUNTRY: United States
DOCUMENT TYPE: (EVALUATION STUDIES)
Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200105
ENTRY DATE: Entered STN: 20010604
Last Updated on STN: 20010604
Entered Medline: 20010531

AB PURPOSE: Previous studies have indicated that high-energy transurethral microwave thermotherapy (TUMT) requires intravenous (IV) sedation and/or narcotics for patient tolerance. This study was performed to determine tolerability, patient acceptance, and efficacy of TUMT using both low- and high-energy protocols in a single United States university setting. MATERIALS AND METHODS: Between August 11, 1997 and October 28, 1999, 210 men (mean age 64.9 +/- 9.1 years) presenting with symptomatic benign prostatic hyperplasia (BPH) received treatment with a Prostatron TUMT using either the low-energy Prostasoft 2.0 or high-energy Prostasoft 2.5 software. Each patient had digital rectal examination and prostate-specific antigen level consistent with BPH, American Urological Association symptom score > or = 15, and Qmax <15 mL/s. Each patient

received TUMT with only **ibuprofen 400 mg** by mouth (PO), lorazepam 1.0 mg PO, and ketorolac 30 mg intramuscularly (IM) prior to TUMT. A few patients who were concerned about limited pain threshold received **oxycodone** 5 mg/acetaminophen 325 mg PO. Of 210 patients treated, 12-month efficacy data were available for analysis in 80 patients. RESULTS: Forty-eight men (mean age 65 +/- 9.2 years) received low-energy 2.0 software TUMT, and 32 men (mean age 65.1 +/- 9.2 years) were treated with high-energy 2.5 software. Mean prostatic volume was 44.3 +/- 23.9 mL and 60.7 +/- 26.4 mL for the 2.0 and 2.5 groups, respectively. Mean energy delivered was 108.8 +/- 50.4 kJ and 173.1 +/- 41.1 kJ for the 2.0 and 2.5 treatment groups, respectively. International Prostate Symptom Score decreased from 23 pre-TUMT to 8 post-TUMT and 21 pre-TUMT to 10 post-TUMT at 12 months in the 2.0 and 2.5 groups, respectively. Mean peak flow rate improved 31.9% from 9.1 mL/s pre-TUMT to 12.0 mL/s post-TUMT and 45.8% from 9.6 mL/s pre-TUMT to 14.0 mL/s post-TUMT at 12 months in the 2.0 and 2.5 groups, respectively. All but two patients tolerated treatment without IV sedation. One patient experienced intolerable rectal spasm, and treatment was terminated in another patient because of poorly controlled hypertension. CONCLUSIONS: Patients can be treated safely with TUMT using either low or high energy, with almost universal patient tolerance and without the need for IV sedation or narcotics, if they premedicated effectively using a PO/IM regimen. Patients experience significant relief of symptoms whether low- or high-energy TUMT is used; however, high-energy TUMT improves flow rate to a greater extent than does low-energy therapy.

L4 ANSWER 15 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 2000-14603 DRUGU S
TITLE: Phenytoin as a possible cause of acetaminophen hepatotoxicity: Case report and review of the literature.
AUTHOR: Brackett C C; Bloch J D
CORPORATE SOURCE: Univ.Ohio-State
LOCATION: Columbus, Ohio, USA
SOURCE: Pharmacotherapy (20, No. 2, 229-33, 2000) 2 Tab. 23 Ref.
CODEN: PHPYDQ ISSN: 0277-0008
AVAIL. OF DOC.: Division of Pharmacy Practice and Administration, College of Pharmacy, The Ohio State University, 500 West 12th Avenue, Columbus, OH 43210, U.S.A.
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 2000-14603 DRUGU S
AB A case of a women who was given phenytoin and experienced acetaminophen hepatoxicity is reported. After discontinuation of acetaminophen the patients liver chemistry returned to normal. The case suggests that caution is warranted when phenytoin and acetaminophen are given concomitantly.
ABEX A 55-yr-old woman presented with severe right-sided chest pain and dyspnea. Physical examination was suggestive of right lower lobe pneumonia. She was released with cefprozil, hydrocodone and acetaminophen. She returned 36 hr later with continued severe chest pain and new onset hemoptysis. Progression of the right lower lobe infiltrate and a new left lobe infiltrate were seen. She was admitted for pneumonia. Drug therapy consisted of phenytoin sodium **400 mg** every other day alternating with 300 mg, warfarin sodium 6 mg/day, diltiazem 30 mg q.i.d., cisapride 20 mg q.i.d., famotidine 40 mg/day, paroxetine 20 mg/day, cefprozil 500 mg b.i.d., **ibuprofen 400 mg** q.i.d. and hydrocodone with acetaminophen as needed. On admission **ibuprofen**, cefprozil, hydrocodone, warfarin and acetaminophen were discontinued. She was given unfractionated heparin as enoxaparin 110 mg s.c. b.i.d. followed by IVC filter on day 8 and then warfarin was reinstituted. She then presented with elevated hepatic transaminases, lactose dehydrogenase and alkaline

phosphatase. She was being given **oxycodone** with acetaminophen 1-2 325 mg tablets every 4 hr as required, propoxyphene napsylate with acetaminophen 1-2 650 mg tablets every 4-6 hr and acetaminophen 500 mg 1-2 tablets every 4-6 hr. All acetaminophen containing drugs were discontinued and she was told to avoid them in the future. (LL)

L4 ANSWER 16 OF 23 MEDLINE on STN DUPLICATE 9
ACCESSION NUMBER: 1999294557 MEDLINE
DOCUMENT NUMBER: PubMed ID: 10368091
TITLE: Additive analgesic effects of **oxycodone** and **ibuprofen** in the oral surgery model.
AUTHOR: Dionne R A
CORPORATE SOURCE: Pain and Neurosensory Mechanisms Branch, National Institute of Dental and Craniofacial Research, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892, USA.. dionne@yoda.nidr.nih.gov
SOURCE: Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons, (1999 Jun) 57 (6) 673-8. Journal code: 8206428. ISSN: 0278-2391.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Abridged Index Medicus Journals; Dental Journals; Priority Journals
ENTRY MONTH: 199906
ENTRY DATE: Entered STN: 19990628
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Entered Medline: 19990616

AB PURPOSE: A traditional approach to achieve greater analgesic efficacy is to combine an efficacious dose of a nonopioid with a dose of an opioid sufficient to produce additive analgesia without a substantial increase in the incidence of adverse effects. This study evaluated the additive analagesic effects of the combination of **ibuprofen** and **oxycodone.** PATIENTS AND METHODS: A dose of **400 mg ibuprofen** was compared with **400 mg ibuprofen** with **oxycodone** in doses of 2.5, 5, or 10 mg in the oral surgery model of acute pain. Analgesic efficacy was measured with category and visual analog scales at 15, 30, 45, and 60 minutes and hourly up to 6 hours. RESULTS: **Ibuprofen** plus 10 mg **oxycodone** produced significantly greater analgesia compared with the other three groups, as measured by the visual analog scale from 15 minutes after drug administration up to the 2-hour observation. All four treatments were similar from 3 to 6 hours, with the area under the pain intensity difference curve being similar across groups. Neither the 2.5-mg nor the 5-mg **oxycodone** dose provided any additive analgesia over **ibuprofen** at any points. Addition of **oxycodone** resulted in a dose-related increase in the number of patients reporting adverse effects, with significantly greater drowsiness and vomiting at the 10-mg dose. CONCLUSIONS: These results indicate that additive analgesia can be achieved for the combination of a nonsteroidal anti-inflammatory drug and an orally effective opioid, with faster onset of relief for the combination of **400 mg ibuprofen** and 10 mg **oxycodone** over the first 2 hours after administration, but at the expense of an increased incidence of adverse events.

L4 ANSWER 17 OF 23 CAPLUS COPYRIGHT 2005 ACS on STN DUPLICATE 10
ACCESSION NUMBER: 1997:589937 CAPLUS
DOCUMENT NUMBER: 127:229606
TITLE: Bromfenac sodium, acetaminophen/**oxycodone**, **ibuprofen**, and placebo for relief of postoperative pain
AUTHOR(S): Johnson, Gary H.; Van Wagoner, J. Dallas; Brown, Jean;

Cooper, Stephen A.
CORPORATE SOURCE: Latter Day Saints Hospital, Salt Lake City, USA
SOURCE: Clinical Therapeutics (1997), 19(3), 507-519
CODEN: CLTHDG; ISSN: 0149-2918
PUBLISHER: Excerpta Medica
DOCUMENT TYPE: Journal
LANGUAGE: English

AB The objective of this double-masked, parallel-group, multicenter, inpatient study was to compare bromfenac with an acetaminophen/**oxycodone** combination and **ibuprofen** in patients who had pain due to abdominal gynecol. surgery. In the 8-h, single-dose phase, 238 patients received single oral doses of bromfenac (50 or 100 mg), acetaminophen 650 mg/**oxycodone** 10 mg, **ibuprofen** **400 mg**, or placebo. In the multiple-dose phase, 204 patients received bromfenac, acetaminophen/**oxycodone**, or **ibuprofen** for up to 5 days. In the single-dose phase, both bromfenac doses produced peak analgesic responses equivalent to acetaminophen/**oxycodone**, but the responses to bromfenac were longer lasting. Bromfenac produced significantly better overall (8-h) analgesic summed scores than acetaminophen/**oxycodone**. **Ibuprofen** was less efficacious than the other analgesics. The remedication rate was lower in both bromfenac groups than in the other treatment groups. The acetaminophen/**oxycodone** group reported more somnolence and vomiting. Single doses of bromfenac provided analgesia at least equivalent to that of the acetaminophen/**oxycodone** combination, with a longer duration of action. Both doses of bromfenac and acetaminophen/**oxycodone** were superior to **ibuprofen** in this study.

REFERENCE COUNT: 30 THERE ARE 30 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L4 ANSWER 18 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 1996-00845 DRUGU T S
TITLE: Intranasal butorphanol-induced apraxia reversed by naloxone.
AUTHOR: Gora-Harper M L; Sunahara J F; Gray M S
CORPORATE SOURCE: Univ.Kentucky
LOCATION: Lexington, Ky., USA
SOURCE: Pharmacotherapy (15, No. 6, 798-800, 1995) 10 Ref.
CODEN: PHPYDQ ISSN: 0277-0008
AVAIL. OF DOC.: Drug Information Center, University of Kentucky Hospital, 800 Rose Street, Lexington, KY 40536-0084, U.S.A.
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 1996-00845 DRUGU T S

AB The case is described where a single dose of intranasal butorphanol tartrate (BP, Stadol, Bristol-Squibb) was associated with apraxia; this was reversed by i.m. naloxone (NX). Other drugs which she had received included prior **ibuprofen**, p.o. **oxycodone** HCl + paracetamol and concomitant cefaclor, phenylpropanolamine + guaifenesin. Cephalosporins, phenylpropanolamine + guaifenesin had previously been taken with no ill effects.

ABEX A 43-yr-old woman who experienced headaches for 2 days and recurrent sinusitis received intranasal BP at 1 spray in each nostril 4 x/day after adequate doses of **ibuprofen** for 2 days had brought no relief. She was also prescribed cefaclor at 500 mg t.i.d. and phenylpropanolamine HCl at 75 mg + guaifenesin at **400 mg** b.i.d., as necessary. She had received p.o. cephalosporins and phenylpropanolamine + guaifenesin in the past without difficulty. At 13.00 hr, she took 1 capsule of **oxycodone** HCl at 5 mg + paracetamol at 500 mg, with little response. At 18.00 hr, she took her 1st dose of cefaclor, phenylpropanolamine + guaifenesin and butorphanol. Within 1 hr, she was supine, and although mentally alert, was unable to move or speak. When she attempted to speak, her lips, velum and tongue would not move under

voluntary control. B.P. was 133/99 mmHg, her respiratory rate 18 breaths/min and her HR 72 b.p.m. Immediately after receiving i.m. NX at 2 mg, she was able to articulate without difficulty and able to move all extremities. She was discharged with a diagnosis of an adverse drug event associated with BP. (E61/MB)

L4 ANSWER 19 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 1994-40129 DRUGU T
TITLE: Gastric retention of enteric-coated magnesium chloride tablets.
AUTHOR: Chapron D J; Korman L B; Barry W L
CORPORATE SOURCE: Univ.Connecticut
LOCATION: Storrs, Newington, Framington, Connecticut, United States
SOURCE: Ann.Pharmacother. (28, No. 7-8, 874-77, 1994) 1 Fig. 24 Ref.
CODEN: APHRER ISSN: 1060-0280
AVAIL. OF DOC.: Pharmacokinetics Laboratory, Room C-2019, Pharmacy Department, MC-2205, University of Connecticut Health Center, Farmington, CT 06030, U.S.A.
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 1994-40129 DRUGU T
AB A case of gastric retention of enteric-coated magnesium chloride tablets (S-MG, Slow-Mag, Searle) in a seriously ill patient is reported. The patient had mild pylorospasm and suspected gastric motor dysfunction which may have been due to concurrent use of **oxycodone** (combined with acetaminophen), alcoholism-induced vagal injury, cisplatin-based chemotherapy of small-cell lung carcinoma and possibly a paraneoplastic neuromuscular syndrome involving the GI tract. S-MG was discontinued and he was started on ketoconazole. Other treatment included etoposide, morphine sulfate extended release, docusate Na, prochlorperazine suppositories, senna, ranitidine, metoclopramide, i.v. Mg hydroxide, Mg sulfate and **ibuprofen.** A seriously ill patient may be a poor candidate for therapy with large enteric-coated medication.
ABEX A 65-yr-old man with small cell lung cancer metastatic to the liver and mediastinum diagnosed 4 mth prior to admission had been treated with cisplatin and etoposide with a PR. Increasing back and right upper quadrant pain was treated with morphine sulfate extended release 30 mg b.i.d. and morphine sulfate elixir 20 mg every 3 hr for breakthrough pain. He also received lactulose, docusate Na, prochlorperazine, senna and ranitidine, but reported increasing pain, nausea, vomiting and anorexia. He had sensory neuropathy secondary to chronic alcohol abuse. Dehydration was presumed and he was treated with NaCl 0.9% hydration, p.o. nutritional supplements, S-MG (64 mg of elemental Mg/tablet) 2 tablets t.i.d., **oxycodone**/acetaminophen, metoclopramide 10 mg t.i.d. for nausea, Mg hydroxide 30 ml for constipation and a phosphate enema when requested. He continued to have nausea and vomiting and Mg concentrations continued to decline. I.v. Mg sulfate 2 g was administered. On day 4, he reported abdominal fullness and gastric distress. X-ray showed multiple circular densities that were identified by endoscopy as intact tablets and presumed to be S-MG. Pyloric spasm and monilial esophagitis were also demonstrated. He was started on ketoconazole **400 mg**/day and S-MG was discontinued. Mg sulfate was given i.v. He was discharged on day 7 on morphine sulfate, metoclopramide, ketoconazole, docusate Na and **ibuprofen** and died a wk later. (E35/JP)

L4 ANSWER 20 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 1993-20415 DRUGU T S
TITLE: Analgesic Efficacy of an **Ibuprofen-Oxycodone** Combination.
AUTHOR: Cooper S A; Haber B; Ilacqua J; Glauda N; Lamp C

LOCATION: Philadelphia, Pennsylvania, United States
SOURCE: Clin.Pharmacol.Ther. (53, No. 2, 172, 1993)
CODEN: CLPTAT ISSN: 0009-9236
AVAIL. OF DOC.: Temple Univ Sch Dentistry, Phila, PA., U.S.A.
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 1993-20415 DRUGU T S
AB The analgesic efficacy of **ibuprofen** + **oxycodone** (IB+OX) was compared with that of IB alone in patients with pain due to surgical removal of impacted teeth in a parallel group, double-blind, placebo-controlled, factorial design clinical trial. Both IB and IB+OX were better than placebo at every hrly observation and for all other measures of efficacy. IB and IB+OX were better than placebo at every hrly observation and for all other measures of efficacy. IB+OX was superior to IB for relief, pain intensity difference (PID) and AUC PID. Compared to IB, IB+OX had the longest time to rescue analgesic and the highest % analgesic responders. The combination also had the highest incidence of side-effects.
ABEX Methods 47 Patients with pain due to surgical removal of impacted teeth received IB+OX (IB **400 mg**; OX 5 mg), 37 IB (**400 mg**) alone and 24 placebo. Results Both IB and IB+OX were better than placebo at every hrly observation and for all other measures of efficacy. IB+OX was superior to IB for relief (hr 4-6), PID (hr 5-6) and AUC PID. Compared to IB, IB+OX had the longest time to rescue analgesic (282 vs. 242 min) and the highest % analgesic responders (68 vs. 51%). The combination also had the highest incidence of side-effects. (PJ).

L4 ANSWER 21 OF 23 DRUGU COPYRIGHT 2005 THE THOMSON CORP on STN
ACCESSION NUMBER: 1991-15869 DRUGU T S
TITLE: Evaluation of Ketorolac, **Ibuprofen**, Acetaminophen and an Acetaminophen-Codeine Combination in Postoperative Oral Surgery Pain.
AUTHOR: Forbes J A; Kehm C J; Grodin C D; Beaver W T
LOCATION: Baltimore, Maryland, Shrewsbury, Pennsylvania, Washington, Columbia,District, United States
SOURCE: Pharmacotherapy (10, No. 6, Pt. 2, 94S-105S, 1990) 4 Fig. 7 Tab. 10 Ref.
CODEN: PHPYDQ ISSN: 0277-0008
AVAIL. OF DOC.: 5 South Main Street, Shrewsbury, PA 17361, U.S.A.
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 1991-15869 DRUGU T S
AB In a randomized, double-blind, parallel group study at 2 sites 206 patients who had impacted 3rd molars removed received (all p.o.) ketorolac tromethamine (KT), **ibuprofen** (IB), acetaminophen (AC), AC + codeine (CD) or placebo for postoperative pain. All active medications had an analgesic effect by 1 hr, which was higher with KT than AC and AC + CD over 6 hr. Backup analgesic consisted of Percocet-5 (**oxycodone** HCl + AC) or Phenaphen (AC + CD). Side-effects of all regimens included drowsiness; for KT included nausea, flushing, breathlessness; for IB included fever, flatus, asthenia; for AC included chills, cramp; for AC + CD included nervousness, flushing, sore throat; for KT and IB included headache; for AC and AC + CD included nausea, emesis; and for all except IB included dizziness.
ABEX Methods 31 Patients (16 male, mean age 22.42 yr, 17-36) with postoperative oral surgery pain received KT (10 mg), 35 (20 male, mean age 21.54 yr, 17-32) KT (20 mg), 32 (13 male, mean age 23.16 yr, 16-37) IB (**400 mg**), 36 (20 male, mean age 22.50 yr, 16-46) AC (600 mg), 38 (17 male, mean age 22.32 yr, 16-48) AC (600 mg) + CD (60

mg) and 34 (18 male, mean age 23.65 yr, 16-45) placebo (dose 1 only) for up to 15 doses except for KT (20 mg) group who received KT (10 mg) for doses 2-15. Patients could use Percocet-5 (AC 325 mg + **oxycodone** HCl 5 mg) or Phenaphen (AC 325 mg + CD phosphate 30 mg) as a backup for pain relief. Results All active medications were superior to placebo for every measure of total and peak analgesia; KT (both doses) and IB were superior to AC or AC + CD, with KTs superiority persisting from hr 1-6. IB was superior to AC and AC + CD by hr 2, until hr 6 for AC and hr 5 for the combination. The analgesic effect was felt by hr 1 with all medications; the effect of AC persisted for 5 hr, and the others for 6 hr. 58% Of patients on KT (10 mg) required remedication by hr 6; the values for KT (20 mg), IB, AC, AC + CD and placebo were 54, 63, 81, 82 and 97%, respectively. On the day of surgery mean pain relief was greater for KT (both doses) and IB than for AC, and greater for KT (20 mg) than for AC + CD. All side-effects were transitory, none required treatment. The number of adverse effects after dose 1 with KT (10 mg), KT (20 mg), IB, AC, AC + CD and placebo were 7, 10, 9, 5, 9 and 0, respectively with sleepiness most common. (K20/JW)

L4 ANSWER 22 OF 23 EMBASE
on STN DUPLICATE 11

ACCESSION NUMBER: 85072128 EMBASE
DOCUMENT NUMBER: 1985072128
TITLE: Analgesia with oral narcotics and added **ibuprofen** in cancer patients.
AUTHOR: Weingart W.A.; Sorkness C.A.; Earhart R.H.
CORPORATE SOURCE: Medical College of Wisconsin, Milwaukee, WI 53706, United States
SOURCE: Clinical Pharmacy, (1985) Vol. 4, No. 1, pp. 53-58.
CODEN: CPHADV
COUNTRY: United States
DOCUMENT TYPE: Journal
FILE SEGMENT: 037 Drug Literature Index
038 Adverse Reactions Titles
024 Anesthesiology
031 Arthritis and Rheumatism
030 Pharmacology
016 Cancer
LANGUAGE: English
ENTRY DATE: Entered STN: 911210
Last Updated on STN: 911210

AB A scheduled regimen of oral narcotic analgesics was compared with a regimen of oral narcotic analgesics plus **ibuprofen** for analgesic efficacy in patients with cancer. Ten patients with metastatic cancer were randomly assigned to receive either **ibuprofen 400 mg** or a look-alike placebo four times daily in addition to each patients' existing regimen of scheduled oral narcotics. A two-period changeover study design was used. The 24-hour narcotic intake equated to injectable morphine was computed for each patient at baseline and during the nine study days. A visual analogue scale was used to evaluate pain relief, nausea, mood depression, daytime drowsiness and nighttime sleeplessness. The analgesic efficacy of the narcotic-**ibuprofen** combination was significantly greater than the analgesic efficacy of the narcotic-placebo combination. Eight patients demonstrated a positive treatment effect with added **ibuprofen**; the overall improvement in analgesia averaged 39.1% in these patients. There was no significant increase from baseline in the incidence of nausea, mood depression, daytime drowsiness or nighttime sleeplessness. At the doses used in this study, a treatment regimen of oral narcotic analgesics plus **ibuprofen** was more effective than oral narcotics alone in relieving pain associated with cancer.

L4 ANSWER 23 OF 23 DRUGU on STN
ACCESSION NUMBER: 1983-24106 DRUGU P T

TITLE: New Peripherally-Acting Oral Analgesic Agents.
AUTHOR: Cooper S A
LOCATION: Newark, New Jersey, United States
SOURCE: Annu.Rev.Pharmacol.Toxicol. (23, 617-47, 1983) 20 Fig. 3 Tab. 79 Ref.
CODEN: ARPTDI ISSN: 0362-1642
AVAIL. OF DOC.: University of Medicine and Dentistry, New Jersey Dental School, 100 Bergen Street, Newark, New Jersey 07103, U.S.A.
LANGUAGE: English
DOCUMENT TYPE: Journal
FIELD AVAIL.: AB; LA; CT
FILE SEGMENT: Literature
AN 1983:24106 DRUGU P T
AB The activity of several new peripherally acting p.o. analgesics is reviewed.
ABEX The drugs were **ibuprofen**, naproxen and naproxen sodium, indoprofen, zomepirac sodium, diflunisal, piroxicam, fenoprofen, fendosal, suprofen, flurbiprofen and ketoprofen. They are compared with aspirin, acetaminophen, toloxamine, promethazine, phenobarbital, codeine, indomethacin, propoxyphene, meprobamate, morphine, **oxycodone** and tolmetin. Side-effects observed tended to be similar to those of aspirin such as platelet inhibition and gastric irritation. The mechanism of action of peripherally-acting analgesics, their use in pain therapy and the methodology and techniques used in the assay of analgesic efficacy are reviewed. **Ibuprofen (400 mg)** was more effective than 650 mg aspirin, 60 mg codeine or 65 mg propoxyphene in surgical dental pain. Side-effects were similar to aspirin, but less severe. Minimal interaction occurred with warfarin or p.o. hypoglycemics. Naproxen (**400 mg**) was only slightly more effective than 600 mg aspirin but more effective than 65 mg propoxyphene in postoperative surgical pain. Indoprofen (100 mg, 200 mg) was found more efficacious than aspirin (300, 600, 1000 mg) in cancer patients and postepisiotomy pain. Both 50 mg and 100 mg zomepirac sodium (structurally related to indomethacin) were more effective than aspirin (650 mg) in postsurgical dental impaction patients. Diflunisal (500 mg and 1000 mg) was found to be more effective than propoxyphene (100 mg) alone or in combination with 650 mg acetaminophaen in dental impaction pain. Suprofen, carprofen, flubiprofen and ketoprofen were all more effective than 650 mg aspirin in dental pain in terms of both peak and total effects.

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(FILE 'HOME' ENTERED AT 14:53:47 ON 29 JUL 2005)

FILE 'CAPLUS, MEDLINE, EMBASE, BIOSIS, DRUGMONOG2, DRUGU' ENTERED AT 14:55:42 ON 29 JUL 2005
L1 6318 S OXYCODONE
L2 798 S L1 AND IBUPROFEN
L3 53 S L2 AND 400 (W) MG
L4 23 DUPLICATE REMOVE L3 (30 DUPLICATES REMOVED)

=> log y

COST IN U.S. DOLLARS	SINCE FILE ENTRY	TOTAL SESSION
FULL ESTIMATED COST	55.33	55.96
DISCOUNT AMOUNTS (FOR QUALIFYING ACCOUNTS)	SINCE FILE ENTRY	TOTAL SESSION
CA SUBSCRIBER PRICE	-6.57	-6.57

STN INTERNATIONAL LOGOFF AT 15:04:45 ON 29 JUL 2005